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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/801,262

03/15/2004

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RATH-012

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04/02/2009

EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

04/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,262	<b>Applicant(s)</b> NIEDZWIECKI ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,10,11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/5/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2, 5-8,10,11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boulos et al. (US Pat. 6,914,073) in view of Gravish et al., Tedeschi et al., Wilcox et al., Duan et al., Murakami et al., Kim, Brevetti (US Pat. 4,968,719), Pertosa et al. and Kawano et al. (US Pat. 3,405,120).

Boulos et al. disclose composition for benefiting cardiovascular health, including slowing the progression of atherosclerosis containing lysine, proline, arginine, Vitamin C, magnesium, green tea, selenium, copper and manganese which can be administered orally as a tablet or capsule which are formulated using various excipients(Column 3, lines 40-55,Column 6, lines 10-20, 40-46, Column 7, lines 65-67, Column 9, lines 8-26, Columns 11, 12).

Gavish et al. disclose that high levels of lipoprotein (a) is associated with atherosclerotic disease and that administration of N-acetylcysteine was effective in lowering plasma levels of lipoprotein (a) (Abstract).

Tedeschi et al. disclose that both Green Tea and vitamin C have antiinflammatory activity (Page 435).

Wilcox et al. disclose that the naringenin, is a citrus flavonoid, which has antiatherogenic properties and that flavonoids have anti-inflammatory properties (Pages 160, 164-166).

Duan et al. discloses that glucosamine increases heparin sulfate proteoglycans in vivo and inhibits atherosclerosis (Abstract).

Murakami et al. disclose that taurine improves serum cholesterol levels and retards the progression of atherosclerosis (Pg. 68, Abstract).

Kim discloses that glucosamine and taurine have anti-inflammatory activity (abstract).

Brevetti disclose the treatment of arteriosclerosis with L-carnitine (Column 2, lines 19-21, Column 3, lines 39-44).

Pertosa et al. disclose a wide range of hemodialysis-related pathologies, including accelerated atherosclerosis, have been associated with oxidative stress and that L-carnitine balances signaling mechanisms underlying the systemic inflammation in hemodialysis (Abstract).

Kawano et al. disclose the treatment of arteriosclerosis and inflammatory rheumatism with chondroitin sulfate (Column 2, lines 1-20).

Boulos et al. disclose composition for benefiting cardiovascular health, including slowing the progression of atherosclerosis containing lysine, proline, arginine, Vitamin C,

Art Unit: 1616

magnesium, green tea, selenium, copper and manganese which can be administered orally as a tablet or capsule which are formulated using various excipients for slowing the progression of atherosclerosis and benefiting cardiovascular health. The difference between Boulos et al. and the claimed invention is that Boulos et al. does not expressly disclose the treatment of inflammation, the addition of acetyl-cysteine or at least one of molybdenum, potassium, citrus bioflavonoids, L-carnitine, glucosamine, taurine or chondroitin sulfate. However, the prior art amply suggests the same as Gavish et al. discloses that acetyl cysteine is effective in lowering high lipoprotein (a) plasma levels, which is a risk factor for atherosclerosis; Tedeschi et al. Vitamin C and Green Tea have anti-inflammatory activity. Further, the prior art discloses and/or suggests that citrus bioflavonids (Wilcox et al.), L-carnitine (Pertosa et al.), glucosamine (Kim; Duan et al.), taurine (Kim; Murakami et al.) and chondroitin sulfate (Kawano et al.) have anti-inflammatory activity and would be effective in slowing the progression of arteriosclerosis or atherosclerosis. As such, it would have been well within the skill of and one of ordinary skill in the art would have expected that the combination of acetyl cysteine, citrus bioflavonids, L-carnitine, glucosamine, taurine and chondroitin sulfate would add to the anti-atherosclerotic activity of the prior art composition and that the prior art composition would also be effective in treating inflammation in view of the anti-inflammatory properties of citrus bioflavonids, L-carnitine, glucosamine, taurine, chondroitin sulfate, green tea and vitamin C.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that not all claim limitations are taught by the prior art, however, the Applicant only cites three references of the references. Further, it would have been well

Art Unit: 1616

within the skill of one ordinary skill in the art to administer various amounts of the claimed compounds based on effectiveness in treating inflammation and/or arteriosclerosis. The Applicant has not provided evidence that the claimed amounts provide unexpected activity. As such, the Applicant's arguments are not sufficient to overcome the rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 2, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616